

REMARKS

This response is submitted in reply to the Office Action mailed October 1, 2010 ("the Action"). Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow. Claims 1-26, 32 and 62-65 were pending in the application. Claims 2, 3, 19 and 63-65 have been canceled. Original Claims 27, 28, 44, 51, 60 and 61 have been re-entered (some with amendments) as Claims 66, 67, 68, 69, 70 and 71, respectively. These original claims were canceled to reduce filing fees at the time of filing subject to re-entry by the Applicant during prosecution as noted in the Preliminary Amendment filed April 21, 2006.

I. The § 112 Rejections

The Action rejects Claims 10-12 and 17 for certain claim informalities. Applicant has amended the claims to obviate the noted informalities and requests that these rejections be withdrawn.

II. The § 102 Rejections

The Action rejects Claims 1, 32 and 62-64 as being anticipated by U.S. Patent No. 7,588,030 to Ede ("Ede"). Ede proposes a frame that holds small cup-like inserts that are pushed upward through a ceiling to release the dry powder. Applicant submits that this is very different from the claimed subject matter which does not use such inserts. Rather, the annular frame, flexible floor and flexible sealing hold the medicine in the blisters so that the dry powder contacts the side walls of the frame. Applicant has amended Claims 1, 32, and 62 to recite that the blister package has an annular shape, includes two rows of concentric apertures (see, e.g., Figures 1C, 1D, 7B of the pending application), and that the blisters, when sealed, are devoid of internal movable components (e.g., cup shaped inserts).

Applicant respectfully submits that Ede teaches away from such a configuration.

Applicant also notes that the term "blister" is used in a broad sense to mean a sealed dry powder well, compartment or receptacle that releasably holds a quantity of a dry powder

(*see, e.g.*, p. 10 of the pending application), *e.g.*, a DCS, which includes both planar floors/ceilings as well as those with shapes such as projections.

In view of the foregoing, Applicant respectfully submits that the claims are not anticipated by, and indeed are patentable, over the cited prior art.

III. The § 103 Rejections

With respect to Claim 65, the Action concedes that Ede fails to teach two generally concentric rows of spaced apart apertures but alleges that this configuration is obvious based on the two rows of wells described by WO/01/68169 to Hickey et al. ("Hickey"). Applicant agrees that inhaler DCS frames with two concentric rows of apertures is known. *See, e.g.*, U.S. Patent No. 6,679,254 to Rand et al. (Rand). However, it is the claimed combination of features that is the proper focus of review for patentability. It is improper to take isolated features from different prior art references and combining them based on the claimed invention, particularly without considering the overall teachings of each reference. Ede requires the use of cup-like inserts and teaches away from the claimed configuration. Hickey does not use cup-like inserts nor two concentric rows or apertures. Applicant submits that Rand does not describe an annular shape (rather a disk shape) and, indeed teaches away from this configuration as it uses gear teeth on an outer perimeter (Fig. 1a). Applicant submits that the Rand pockets have a closed bottom provided by the lower surface of the frame which includes a spiral guide to access the different rows (does not include the through holes sealed by both upper and lower flexible layers). Thus, Rand also appears to propose closed bottom pockets with a flexible upper cover. *See, Figures 1a, 1b of Rand.*

With respect to the rotatable gear (*e.g.*, Claim 12), the Action cites the combination of Ede, Hickey and U.S. Patent No. 4,627,432 to Newell et al. ("Newell") to reject this claim. The Action concedes that Ede and Hickey fail to teach a gear in the center window and attached to the frame member so that the blister package rotates with the gear. The Action however, then cites to Newell for teaching a rotatable gear 12 with gear teeth (notches). The Action concludes that it would have been obvious to modify the rotary means of Hickey with

the centered gear per Newell "to provide a rotary means that won't interfere with the electrical traces and couplings." Action, p. 11. Applicant respectfully disagrees.

The gear of Newell does not reside inside a center space of annular members. Rather, the blister package 7 has a closed center and its blisters extend above the frame openings in the frame 10 (the frame resides over the sealed blister package it is not part of the blister package). Newell fails to resolve the deficiencies of Ede and Hickey.

Regarding Claim 24 With respect to the angled sidewall, the Action alleges that Ede (col. 10, lines 25-38) teaches this feature. Applicant strongly disagrees. Ede states that at the holes are punched, the walls are nominally orthogonal to the face and this "is preferred in most cases." (col. 10, line 27). Ede goes on to say that holes which are slightly larger at the face can provide less resistance (col. 10, lines 28-30) and that the preferred angle is between straight (90 degrees to the face) and 3 degrees from straight, more preferably 1 degree (col. 10, lines 30-38). Applicant submits that Ede teaches away from the angles, particularly the larger angles recited in Claim 25 and 70 in that Ede configures the apertures to slidably hold the inserts (which need to be retained in the channel and also be able to be pushed out).

With respect to Claim 25, the Action states that Casper (2007/0181124) teaches inclined walls of a blister (citing Figs. 5a, 5b). This may be true, but the walls are not formed in a rigid frame member. Absent the teachings of the instant application, one of skill in the art would not have modified the nominally angled insert channel of Ede to have this angled configuration as Ede clearly teaches away from this configuration and such would appear to render the inserts of Ede to be inoperable. Applicant submits that Claims 25, 68 and 70 are independently patentable over the cited prior art.

Applicant respectfully submits that the Action combines different references based on the teachings of the instant invention. Applicant respectfully reminds the Examiner that selective combination of references based only on the suggestions of the instant application is improper. "Hindsight is a tempting but forbidden zone." *Loctite Corp. v. Ultraseal Ltd.*, 228, USPQ 90, 98 (Fed. Cir. 1985). The standard of obviousness is not whether, in hindsight, it seems elementary that someone would have combined the elements in the prior art to form

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the invention in question. *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983).

Again, the fact that the invention employs known elements does not preclude patentability. It is the claimed combination of elements which is the proper basis for review. “Virtually all inventions are necessarily combinations of old elements.” *Panduit* at 1575 (citing *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 220 USPQ 97, 99-100 (Fed. Cir. 1983)). Indeed, the Federal Circuit has stated (in regard to an obviousness-type invalidity challenge to an issued patent) that “[t]he notion, therefore, that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, §103.” *Panduit* at 1575.

Applicant respectfully submits that the claims are patentable over the cited prior art.

IV. Supplemental Information Disclosure Statement

Applicant is submitting a Supplemental IDS herewith. Applicant respectfully requests that the Examiner consider the listed art and return an initialed form to the undersigned confirming this action.

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CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

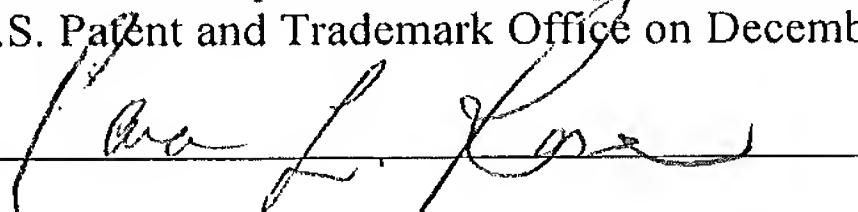


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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on December 6, 2010.

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Cara L. Rose